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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/591,561	06/13/2000	Martin B. Wax	P-3023-US1	7525

7590 12/17/2001

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EXAMINER
O HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	8

DATE MAILED: 12/17/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/591,561	WAX ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *3-10 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,11-14,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

1. Claims 1-17 are pending in the instant application. Claims 1, 16 and 17 have been amended as requested by Applicant in Paper Number 7, filed Oct. 1, 2001.

Election/Restrictions

2. Applicant's election with traverse of Group V, directed to anti-TNFα antibody, which includes claim 14, directed to the monoclonal antibody infliximab, is acknowledged. The traversal is on the ground(s) that the subject matter of the other groups may be searched together with the subject matter of the anti-TNFα antibody group and hence would not be a burdensome search for the Examiner. This is not found persuasive because there were twenty two other compounds or methods claimed that could treat glaucoma, and though some may overlap in the search with the antibody, individual searches would have to be done for all the groups, and to search all twenty four groups would be a burden.

The requirement is still deemed proper and is therefore made FINAL.

The claims which are readable on the elected species are claims 1, 2, 11-14, 16 and 17, with claims 1, 2, 11, 16 and 17 being generic.

Therefore, claims 3-10 and 15 are withdrawn as directed to a non-elected species.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: Priority to Application Number 09/500,023 has been claimed under both 35 U.S.C. 119(e) and 35 U.S.C. 120, and it is only entitled to priority under 35 U.S.C. 120.

Priority

4. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

Specification

5. The disclosure is objected to because of the following informalities: in the legend to Figure 13 on page 9, on the third line is written "TNF-□", which should be changed to "TNF- α".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 2, 11-14, 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 11-14, 16 and 17 are vague and indefinite because claim 1 is an incomplete claim. There is no recitation of the amount of compound to be administered, or what the desired effect is.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 1, 2, 11, 12, 13, 16 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Ron et al., PN 6,204,270.

Claims 1, 2, 11, 12, 13, 16 and 17 encompass a method for treating a subject with glaucoma by administering a compound which antagonizes, inhibits, inactivates, reduces, suppresses and/or limits the release, synthesis or production of TNF-α, a composition containing said compound and further comprising a diluent and suitable carrier, and a method of

administration, wherein the compound that inhibits may be an anti- TNF-α antibody, and may be administered ocularly.

Ron et al. disclose that TNF-α may mediate various ocular disorders including glaucoma, and teach methods of treatment and compositions comprising anti- TNF-α antibodies. See the entire patent, and especially column 1, lines 28-31, column 2, line 13 and lines 51-56, column 3, lines 36-59, column 3, line 65 to column 4, line 30, column 4 line 54 to column 5 line 19, and claims 1 and 14-16. Therefore, Ron et al. anticipates the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ron et al., PN 6,204,270, as applied to claims 1, 2, 11, 12, 13, 16 and 17 above, and further in view of Tobinick, PN 6,177,077.

Claims 1, 2, 11, 12, 13, 16 and 17 are described above. Claim 14 encompasses a method of treating a subject with glaucoma by administering a compound which antagonizes, inhibits, inactivates, reduces, suppresses and/or limits the release, synthesis or production of TNF- α, wherein the molecule is infliximab.

The teachings of Ron et al. are described above. Ron et al. does not specifically teach that the anti-TNF-α antibody used to treat glaucoma may be infliximab.

Tobinick teaches that the commercially available chimeric anti-TNF monoclonal antibody infliximab is a specific inhibitor of TNF, and may provide the possibility of therapeutic intervention in TNF mediated diseases (see column 2, lines 9-21 and lines 55-60, and column 5, line 51).

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art of cytokines and their receptors at the time the invention was made, to use infliximab to treat glaucoma, since Ron et al. teach that TNF-α may mediate various ocular disorders including glaucoma which may be treated by anti-TNF-α antibodies, and Tobinick teaches that infliximab is a powerful TNF blocker. Since infliximab has been shown to be effective in treating other TNF mediated disorders, the skilled artisan would have a reasonable expectation of success, and a further advantage is that infliximab is a commercial product and is therefore easily available.

Conclusion

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242.

Informal papers filed by fax should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

LORRAINE SPECTOR
PRIMARY EXAMINER